23-629
(Judge Armando O. Bonilla)

IN THE UNITED STATES COURT OF FEDERAL CLAIMS

VANDA PHARMACEUTICALS, INC.,

Plaintiff

v.

UNITED STATES,

Defendant.

BRIEF FOR THE ASSOCIATION FOR ACCESSIBLE MEDICINES AS *AMICUS CURIAE* IN SUPPORT OF THE UNITED STATES' MOTION FOR JUDGMENT ON THE PLEADINGS

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INTEREST OF THE *AMICUS CURIAE*[1]

The Association for Accessible Medicines (AAM) is a nonprofit, voluntary association representing manufacturers and distributors of generic and biosimilar medicines and bulk active pharmaceutical chemicals, as well as suppliers of other goods and services to the generic pharmaceutical industry. AAM's members provide patients with access to safe and effective generic and biosimilar medicines at affordable prices. AAM's core mission is to improve the lives of patients by providing timely access to safe, effective, and affordable prescription medicines. Generic drugs constitute more than 90% of all prescriptions dispensed in the United States, yet generics account for only 18% of total drug spending.

AAM regularly participates in litigation as an *amicus curiae*. AAM and its members have a significant interest in the questions presented in this litigation, which directly implicate the ability of generic and biosimilar manufacturers to pursue applications to market their products with the FDA. Vanda's attempt to turn basic quality-assurance criteria, developed in conjunction with FDA, into trade secrets held as a property right by the first manufacturer that secures FDA approval could severely undermine the processes that Congress established to allow for efficient review of follow-on generic and biosimilar products. Likewise, Vanda's contention that basic scientific questions about a generic product may amount to an unlawful disclosure of the brand's trade secrets threatens to chill necessary communications that are inherent to the drug-approval process. In the course of developing and bringing to market safe, effective, and competitively priced generics and biosimilars, AAM's members engage in iterative communication with FDA about their proposed products. Clear communication by FDA about proposed products ensures that the

[1] No counsel for a party authored this brief in whole or in part, and no party, party's counsel, or person or entity other than AAM or its counsel contributed money that was intended to fund the preparation or submission of this brief.

generic drug is consistent with the safety and efficacy standards mandated by Congress and expected by the American people. Vanda's novel effort to convert regulatory testing parameters into a property right and to turn basic scientific review questions into improper disclosures would jeopardize the efficiency of this process, undermine consistency in agency decision-making, and ultimately impede patient access to lower-cost generic and biosimilar medicines without any offsetting benefits for innovation.

Because AAM and its members have a strong interest in ensuring that FDA's review process is not unduly restricted by overly broad conceptions of trade secrets, AAM respectfully submits this brief to aid the Court in disposition of the United States' motion for judgment on the pleadings (ECF No. 29).

INTRODUCTION

The American healthcare system, and millions of patients, depend on access to safe, affordable medicines. Manufacturers of generic and biosimilar pharmaceutical products play a critical role in ensuring that competitively priced and effective medicines enter and remain available in the market. Before a generic drug can launch, generic drug manufacturers engage in lengthy negotiations with FDA to ensure that the generic drug will be as safe and effective as the corresponding brand drug, referred to as the Reference Listed Drug (RLD).[2] FDA's communications with generic drug manufacturers facilitate efficiency in the shared project of ensuring that the generic drug supply is as safe and effective as the supply of branded drugs.

ANDAs include extensive scientific testing data, comparing the proposed ANDA product with samples of the RLD and providing information to verify quality control. Among other

[2] Because Vanda's claims in this case involves the review of generic drug applications, AAM discusses the statutory framework and uses the terminology applicable to that process. Similar considerations and concerns apply, however, to the review process for biosimilar medicines. *See* 42 U.S.C. § 262(k).

information, ANDA manufacturers must submit dissolution specifications to measure the amount of the drug in a batch that must be dissolved in a specified amount of time—a quality check to ensure that the drug performs as expected in the body. *See* 21 C.F.R. §§ 211.165, 314.94(a)(9)(i). In the experience of AAM's members, determination of the appropriate dissolution specification is often an iterative process: The generic manufacturer must propose a dissolution-specification in its ANDA, but as with other testing parameters, FDA regularly requires adjustments before the agency is satisfied that the specification is sufficient to ensure batch-to-batch consistency and equivalence. Likewise, during its review process, FDA also regularly asks questions of applicants about other quality control measures relevant to its product. For example, FDA may reference published literature related to certain drug products to ensure that ANDA applicants are prepared to detect and control impurities.

The sweeping theories of property rights and Fifth Amendment takings liability that Vanda asserts in this case threaten to grind this iterative process to a halt, compromising effective communication between FDA with ANDA filers about critical aspects of their applications. If FDA is prevented from effectively communicating with ANDA filers regarding regulatory parameters developed in collaboration with the agency itself, or referencing publicly-available scientific literature related to a drug product, the review process will be undermined. A process that Congress designed to be "streamlined," *Takeda Pharms. USA, Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 629 (Fed. Cir. 2015), would become less efficient and the quality of agency decision-making could be compromised. No offsetting interest justifies this disruption. There is no innovation by the brand manufacturer related to the approved dissolution specification or similar quality-control parameters that merits protection merely because it went through the FDA review process first.

As the United States explains in its motion, Vanda does not have a cognizable property interest in any of the information that it alleges FDA disclosed. The Court should not expand current law and adopt Vanda's novel theories of property rights, which would undermine the drug-approval system that Congress designed. AAM accordingly urges the Court to grant the United States' motion for judgment on the pleadings.

ARGUMENT

I. Vanda's novel theory of property rights would interfere with Congress' framework for generic-drug approval.

Four decades ago, Congress enacted the Hatch-Waxman Act to "expedite the marketing" of low-cost generic drugs. *Teva Pharms. USA, Inc. v. Leavitt*, 548 F.3d 103, 104 (D.C. Cir. 2008). A core insight of the law is that generic manufacturers (and FDA) should not be required to needlessly duplicate the work undertaken by brand manufacturers to show that the brand version of the product is safe and effective. Thus, the law allows a generic competitor to file an abbreviated application "piggy-backing on the brand's" approval, with the generic drug required to show that it "has the same active ingredients as, and is biologically equivalent to, the brand-name drug." *Caraco Pharm. Labs. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012). The landmark legislation has proven enormously successful, with the use of generic drugs saving patients and the U.S. health care system almost $3 trillion dollars over the last decade alone.[3] More recent legislation establishing an abbreviated pathway for biosimilars has been similarly impactful, resulting in savings of nearly $24 billion since 2015.[4]

[3] *See* AAM, *Hatch-Waxman Turns 40.*, (Feb. 2024), https://accessiblemeds.org/sites/default/files/2024-02/AAM-Hatch-Waxman-White-Paper.pdf.

[4] *See* AAM, *The U.S. Generic & Biosimilar Medicines Savings Report,* at 2 (Sept. 2023), https://accessiblemeds.org/sites/default/files/2023-09/AAM-2023-Generic-Biosimilar-Medicines-Savings-Report-web.pdf.

Vanda's novel Fifth Amendment claims in this case seeks to throw sand in the gears of this well-worn system. Seeking to leverage the fact that generic drugs inevitably mirror their brand counterparts in critical respects, Vanda tries to claim a property interest in basic quality-testing parameters that are negotiated with FDA as part of the drug-approval process, and also to assert that references to publicly available scientific facts related to the drug product may reveal the brand's trade secrets merely because they are also addressed in the brand's NDA. Vanda essentially argues that, when reviewing generic drug applications, FDA must ignore what it has learned from approval of the brand drug about the product's characteristics and quality control—including guidance that FDA provided to the brand—because it takes the brand's property right. If such a broad understanding of property rights were adopted, it would substantially disrupt the efficient review process that Congress created in the Hatch-Waxman Act.

A. Brand manufacturers should not be permitted to disrupt generic approval by claiming trade-secret protection in a dissolution specification or similar quality-control parameters approved by FDA.

Product-quality controls for drug products, such as dissolution specifications, are adopted as part of an iterative review process with FDA. Drug sponsors propose dissolution specifications in their applications, *see* 21 C.F.R. §§ 314.50(d)(1)(ii)(a), 314.94(a)(9)(i), but those specifications are typically modified during the course of review, with FDA often proposing that drug manufacturers should tighten the parameters to ensure effective quality control. As the United States explains, that is precisely what happened here. Every manufacturer for the subject drug products, including Vanda, proposed a dissolution specification that FDA did not accept, as the agency instead recommended a stricter specification for each drug product, which the manufacturer then adopted. *See* ECF No. 42 ("U.S. Mot.") 12–13. But while the dissolution specification is routinely set in dialogue with FDA, there are also a limited number of options. For immediate-release products, like those at issue here, FDA typically approves specifications that

range between 75% and 85% in multiples of five (*i.e.*, 75%, 80%, 85%), with only occasional variation.[5]

For their part, generic manufacturers must also submit dissolution specifications, along with other testing parameters. *See* 21 C.F.R. § 314.94(a)(9)(i). They base their proposal on data they have generated, relying on testing of both their own ANDA product and of the corresponding brand product. *See* U.S. Food & Drug Admin., *Guidance for Industry: Dissolution Testing of Immediate Release Solid Oral Dosage Forms*, at 3, 5–6 (Aug. 1997), www.fda.gov/media/70936/download ("*Dissolution Testing Guidance*"); *accord* U.S. Mot. at 7. But although generic manufacturers provide their own data and propose a specification for their own formulation (which could differ from the brand in certain respects, such as with regard to inactive ingredients), in practice "the dissolution specifications are generally the same as the reference listed drug." *Dissolution Testing Guidance*, at 3. That is not surprising, since the premise of the Hatch-Waxman regime is that generic drugs must be bioequivalent to the corresponding brand drug, which requires a common release profile for the active ingredient. *See* 21 C.F.R. §§ 314.3, 314.94(a)(7).

Considering these features of the regulatory regime together lays bare the audacity of Vanda's property claims and the detrimental impact endorsing them would have on generic drug

[5] McAllister *et al.*, *Developing Clinically Relevant Dissolution Specifications for Oral Drug Products—Industrial and Regulatory Perspectives*, PHARMS., Dec. 2020, at 6 ("For immediate release solid oral dosage forms, ….the mean dissolution of 12 units minus 10%, rounded to the nearest 5%, should be used as the Q value and set as Q = 75%, 80% of 85% in 15/30/45 min."); *see also* U.S. Food & Drug Admin, *Guidance for Industry: Dissolution Testing and Acceptance Criteria for Immediate-Release Solid Oral Dosage Form Drug Products Containing High Solubility Drug Substances*, at 5 (Aug. 2018), www.fda.gov/media/92988/download ("For immediate release solid oral drug products containing a high solubility drug substance (as defined herein), the dissolution criterion is Q=80% in 30 minutes."); U.S. Food & Drug Admin, *Guidance for Industry: Good ANDA Submission Practices*, at 21–22 (Jan. 2022), www.fda.gov/media/110689/download.

approval. The dissolution specification for Vanda's NDA is not the result of Vanda's innovation or unique investment. Rather, it emerged through active dialogue with FDA, based on the agency's assessment—not Vanda's—of the proper specification to ensure quality control for the product at issue. Yet Vanda claims that once FDA determined the proper specification for its product, out of the limited set of possible options, the agency may not consider its own previous determination to guide follow-on generic applicants, whose products will—by congressional design—mirror the brand product in dissolution rate. There is no basis for Vanda to claim a property right in what is effectively an agency-determined testing requirement. A brand manufacturer does not secure a property right in the approval conditions set by FDA just because it received FDA's guidance first.

Vanda's claim of ownership of the dissolution specification is especially specious when considering the public nature of many aspects of the dissolution specification. First, as the United States explains, the dissolution method and the time point for the dissolution specification are all publicly disclosed on FDA's website[6] and regularly compiled in product-specific guidance for drugs sharing a particular active ingredient. *See* U.S. Mot. 8–9. Second, the dissolution specification itself also is typically published in the United States Pharmacopeia, *id.* at 9, 23–24, at which point that USP standard is generally understood to guide dissolution specifications for generics. *See Dissolution Testing Guidance*, at 5. Vanda thus has no enduring expectation of a "right to exclude others" from the dissolution specification. *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1011 (1984). Rather, it claims a property right in one narrow component of dissolution testing—*i.e.*, where the specification has been set, likely in the range between 75%–85%—for the limited period of time before that specification is publicized. There is no basis for conferring trade-secretion protection in this unusual context.

[6] *See generally* U.S. Food & Drug Admin, Dissolution Methods Database, www.accessdata.fda.gov/scripts/cder/dissolution/index.cfm (last visited June 27, 2024).

B. Recognizing Vanda's asserted property claims would interfere with dialogue between FDA and generic drug applicants that is essential to the review process.

Effective dialogue between the sponsors of drug applications and FDA is an essential aspect of the drug-approval process. FDA rarely approves an application as first submitted. Rather, the agency actively engages with drug sponsors to ask questions about the submission and identify areas for follow-up. *See generally* 21 C.F.R. § 314.102; Small Bus. and Indus. Assistance, *FDA/CDER SBIA Chronicles*: *Best Communications Practices with FDA* (Jan. 21, 2016), www.fda.gov/media/95830/download. By regulation, FDA is committed to "make every reasonable effort to communicate promptly to applicants easily correctable deficiencies" on matters such as "controls issues," as well as to "promptly" inform applicants of the agency's "need for more data or information or for technical changes in the application or the abbreviated application to facilitate the agency's review." 21 C.F.R. § 314.102(b). Vanda itself plainly benefited from this collaborative approach, as FDA provided feedback on its proposed dissolution specification, among other things. *See* p. 5, *supra*. Yet Vanda's claimed property right would compromise "FDA's ability to provide … generic manufacturers with … comparable assistance." Op. & Order at 11, ECF No. 17.

Consider the implications for Vanda's claim to own the dissolution specification. If Vanda were to prevail, it would effectively preclude FDA from communicating with generic manufacturers about the dissolution specification of their ANDA products because doing so would potentially reveal the specification for the therapeutically equivalent brand product that was set by FDA. *See* Compl. ¶¶ 98–114. Instead, FDA at most could only communicate that it found the proposed specification insufficient, leaving the generic applicant to guess the parameters that the agency prefers. The applicant likely could arrive at the correct answer eventually, since there typically are only a fixed, small number of options. *See* pp. 5-6, *supra*. But the process would be

slower and serve no conceivable purpose, aside from the brand manufacturer's interest in generic delay—delay that would unduly restrict generic competition and millions of dollars of savings to the healthcare system.

Vanda's property theories would also have troubling implications beyond the specific context of dissolution specifications. In their submissions, generic applicants present FDA with a compendium of testing data on the proposed generic product and the RLD.[7] FDA sifts through that data and communicates with the generic drug manufacturer about how to alter the generic's application to ensure that the generic drug is safe and effective.[8] In the process of doing so, FDA reviewers naturally draw from accumulated knowledge about a product and may highlight public sources that, for example, implicate the existence of impurities in a drug product. Such routine communications have never been considered a potential taking under the Fifth Amendment, based on the theory that they might provide a hint to the generic manufacturer about the brand's formulation or manufacturing process. If merely asking scientific questions and drawing attention to publicly available scientific literature or patent applications are construed to give away trade secrets "by implication" or "signaling," ECF No. 11 at 25–27 (Vanda motion to dismiss opposition), robust communication between the agency and generic applicants will inevitably be chilled.

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[7] *See, e.g.*, U.S. Food & Drug Admin, *Guidance for Industry, Referencing Approved Drug Products in ANDA Submissions*, at 7–8 (Oct. 2020), www.fda.gov/media/102360/download?attachment; U.S. Food & Drug Admin, *Draft Guidance for Industry, Sameness Evaluations in an ANDA — Active Ingredients Guidance for Industry*, at 7–9 (Nov. 2022), www.fda.gov/media/163018/download.

[8] U.S. Food & Drug Admin., et al., *Prioritizing Public Health: The FDA's Role In The Generic Drug Marketplace*, (Sept. 26, 2016), www.fda.gov/news-events/congressional-testimony/prioritizing-public-health-fdas-role-generic-drug-marketplace-09262016 ("*Prioritizing Public Health*") (statement of Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research, FDA); U.S. Food & Drug Admin., *Guidance for Industry, Controlled Correspondence Related to Generic Drug Development*, (Mar. 2024), //www.fda.gov/media/164111/download.

AAM respectfully submits that to avoid this effect, it is important for the Court to grant the United States' motion for judgment on the pleadings rather than to defer a decision until after discovery. Discovery in a matter like this consumes significant agency resources, and the prospect that ordinary communications like those at issue here may support a takings claim that survives the pleading stage risks distorting the review process, as FDA reviewers may become hesitant to offer transparent guidance to generic applicants lest they inadvertently trigger years of litigation.

C. FDA should not be prevented from reviewing its previous decisions to ensure consistent and efficient decision-making.

Vanda's attempt to secure ownership in quality-control protocols for a product negotiated with FDA for a drug product would also wreak havoc on the quality of agency review. As a matter of basic administrative law, FDA is not just permitted, but required, to recommend that all companies attempting to manufacture and market the same drug comply with the same regulatory frameworks. "A fundamental norm of administrative procedure requires an agency to treat like cases alike." *Westar Energy, Inc. v. Fed. Energy Regul. Comm'n*, 473 F.3d 1239, 1241 (D.C. Cir. 2007). Agencies must thus not only be aware of and acknowledge their previous decisions involving similarly situated parties, but they must explain and justify any departures from past practice. *See, e.g.*, *Am. Wild Horse Preservation Campaign v. Perdue*, 873 F.3d 914, 927–28 (D.C. Cir. 2017) (collecting decisions vacating agency decisions for failure to acknowledge and explain departures from agency precedent).

This core principle of administrative consistency is essential to FDA review of drug products. Indeed, the entire premise of the Hatch-Waxman regime is that FDA can and should build on its previous approval decisions: FDA's previous finding that a brand drug is safe and effective for its intended use is treated as determinative that a generic version of the drug is safe and effective too, provided the agency finds the products are the "same" in all relevant respects.

Mutual Pharm. Co. v. Bartlett, 570 U.S. 472, 477 (2013). FDA is thus charged with ensuring that generic drugs will perform the same as the corresponding brand, regardless of which company manufacturers it. *See* Uhl *et al.*, *How the FDA Ensures High-Quality Generic Drugs*, 11 Am. Fam. Physician 696–97 (2018) ("When a patient picks up a prescription at a pharmacy and receives a generic medication, FDA approval ensures that the generic drug works the same as the brand name drug."). The agency's review process for generic drugs would be substantially compromised if FDA were prohibited from reviewing and referencing its own previous approval decisions and guidance for earlier drug applications with the same active ingredient. Under Vanda's theory of ownership (*e.g.*, Compl. ¶¶ 116–22), FDA could no longer provide its critical guarantee to the public that every drug applicant, brand or generic, has been held to one high regulatory standard before the drug is made available for sale. Moreover, requiring FDA reviewers to reinvent the wheel when reviewing applications for the same drug substance would inevitably either require an increase in agency resources or result in longer review periods, delaying public access to lower-cost generic alternatives.

Notably, as the United States observes (U.S. Mot. at 22 n.9), Vanda itself has argued in other litigation that FDA *must* consider dissolution testing and similar data from similarly situated applicants (including the brand) when evaluating a generic drug application. In that case, Vanda contends that "[a] generic drug cannot, by definition," establish bioequivalence if the results in its dissolution data "are so widely divergent from *the FDA's own analysis* of the rate and extent of absorption of the listed [*i.e.*, brand] drug" and other generic applicants. Mem. in Supp. of Pl.'s Mot. for Summ. J. at 22, *Vanda Pharms.*, No. 23-cv-2812, ECF No. 24-1. And Vanda further insists that any failure by FDA to "consider known dissolution" and other data from other applications under review (including Vanda's own) "would itself be arbitrary and capricious"

because an agency "is obligated to consider evidence at its disposal that bears on the problem before it." *Id.* at 23. Vanda's inconsistent positions reveal the significant risk inherent in recognizing its broad ownership claims. Brand manufacturers may seek to weaponize their asserted ownership over previous FDA recommendations to block agency consideration of relevant information for generic applications, and then turn around to challenge FDA approval decisions under the APA. Vanda's own litigation history shows this threat is very real.[9]

II. Vanda's asserted property claims would disrupt generic approvals without doing anything to incentivize innovation.

Vanda's claim for property rights in quality-control specifications that emerge from dialogue with FDA in the review process would undermine the Hatch-Waxman regime with no offsetting benefits for innovation. The Court should reject Vanda's attempt to short-circuit the process for reviewing generic drugs with a theory that grants a windfall to brand manufacturers that Congress never contemplated.

"In passing the Hatch-Waxman Act, Congress "attempted to balance the goal of making available more low cost generic drugs with the value of patent monopolies in incentivizing beneficial pharmaceutical advancement." *Mylan Inc. v. Comm'r*, 76 F.4th 230, 234 (3d Cir. 2023) (citations omitted). Thus, while the Act seeks to expedite generic entry, Congress also provided protections for brand manufacturers' investments and intellectual property. Generic manufacturers must make certifications to patents listed by the brand manufacturer in connection with their products, subjecting a generic manufacturer to a potential infringement suit if it seeks to market its product before the listed patents expire. *See Celgene Corp. v. Mylan Pharms., Inc.*, 17 F.4th

[9] With respect to tasimelteon alone, Vanda has filed two different suits against FDA seeking to challenge the agency's approval of generic applications, in addition to multiple (unsuccessful) patent actions. *See Vanda Pharms. Inc. v. FDA*, No. 23-cv-2812 (D.D.C.); *Vanda Pharms. Inc. v. FDA*, No. 23-cv-280 (D.D.C.); *see also Vanda Pharms. Inc. v. Teva Pharms. USA, Inc.*, No. 2023-1247, 2023 WL 3335538 (Fed. Cir. May 10, 2023).

1111, 1117 (Fed. Cir. 2021) (discussing the statutory framework). Congress also provided brand manufacturers with potential regulatory exclusivities for their investments in new innovations, such for obtaining approval of a new chemical entity or investing in a new clinical trial to secure approval for a new product indication. *See* 21 U.S.C. § 355(c)(3)(E)(ii)–(iv).

By contrast, there is no basis to reward Vanda for the development of quality-control parameters like dissolution specifications, which are set based on guidance from FDA. As discussed, p. 5, *supra*, manufacturers must propose dissolution specifications in their applications, and those specifications are then often adjusted based on FDA's direction, as occurred here with Vanda. There is thus no innovation, or indeed meaningful private investment, in the development of an FDA mandated quality-control parameter like a dissolution specification. Moreover, as the United States explains (U.S. Mot. 27–31), any value associated with the dissolution specification is directly tied to its role in the regulatory process—it is not a business secret with independent value developed by manufacturers for their own purposes. To a significant extent, the specification was developed by FDA for FDA's purposes. Brand manufacturers like Vanda should not acquire cognizable property interests in FDA's directives merely because they then incorporate them into their own processes. *Cf. Ukrainian Future Credit Union v. Seikaly*, No. 17-CV-11483, 2017 WL 5665960, at *10 (E.D. Mich. Nov. 27, 2017) (finding no trade secret where the information at issue was valuable only because a regulation barred its disclosure, rather than because the information conferred some intrinsic competitive advantage).

It is one thing for the introduction of generic drugs to be delayed when there is an actual countervailing interest at stake in terms of rewarding innovation. Recognizing the type of property claims asserted by Vanda here would further no such interests, but would only stand in the way of

the efficient review and approval of low-cost generic drugs, to the detriment of patients and the broader healthcare system.

CONCLUSION

For the foregoing reasons and the reasons set forth in the motion of the United States, the Court should grant the United States' motion for judgment on the pleadings.

Dated: June 28, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 28th day of June 2024, I caused the Brief for Association for Accessible Medicines as *Amicus Curiae* in Support of the United States' Motion for Judgment on the pleadings to be served upon the parties through the Court's electronic filing system.

/s/ *Joshuah R. Turner*

Joshuah R. Turner